DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 12, 2015

Covidien LLC
Ms. Rebecca Magnanimo
Regulatory Affairs Product Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K143598
Trade/Device Name: Lapro-Clip™ Auto Suture™ Reusable Long Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: February 10, 2015
Received: February 12, 2015

Dear Ms. Magnanimo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143598

Device Name
Lapro-Clip™ Auto Suture™ Reusable Long Clip Applier

Indications for Use *(Describe)*
Lapro-Clip™ absorbable ligating clip cartridges are intended for use as absorbable ligatures. Lapro-Clip™ absorbable ligating clip cartridges are radio transparent and will not interfere with interpretations of postoperative X-ray, CT, or MRI scans. The Lapro-Clip™ absorbable ligating clip cartridge may be used for ligation of the cystic artery and cystic duct and other general ligation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

SUBMITTER:	Covidien llc 60 Middletown Avenue North Haven, CT 06473 USA
CONTACT PERSON:	Rebecca Magnanimo Regulatory Affairs Product Specialist Covidien llc Phone: (203) 492-6479 Fax: (203) 492-5029 e-mail: Rebecca.magnanimo@covidien.com
DATE PREPARED:	12/17/14
PRODUCT CODE:	GDO and FZP
REGULATION NUMBER:	21 CFR 878.4800 and 878.4300
TRADE/PROPRIETARY NAME:	Lapro-Clip™ Auto Suture™ Reusable Long Clip Applier
COMMON/USUAL NAME:	Absorbable Clip Applier
CLASSIFICATION NAME:	Laparoscope, General & Plastic Surgery
PREDICATE DEVICES:	Lapro-Clip™ Auto Suture™ Reusable Standard and Short Clip Applier (K925602)
DEVICE DESCRIPTION:	The Lapro-Clip™ absorbable ligating clip is delivered by a single use cartridge and actuated by a reusable applier. Lapro-Clip™ absorbable ligating clip cartridges are molded from two polymers: polyglycolic acid and polyglyconate. The outer body is polyglycolic acid and slides over a polyglyconate inner track. Lapro-Clip™ absorbable ligating clips are supplied sterile and undyed. Lapro-Clip™ absorbable ligating clip cartridges are available in two sizes, Medium/Large and Large. Clips are supplied one clip per single use cartridge with either one, two, or six cartridges per sterile package. The Lapro-Clip™ reusable clip appliers are available in three sizes: The Lapro-Clip™ short reusable clip applier is 11cm in length with a shaft diameter of 10mm. The Lapro-Clip™ standard reusable clip applier is 26.5cm in length with a shaft diameter of 10mm. The Lapro-Clip™ long reusable clip applier is 33cm in length with a shaft diameter of 10mm.

INTENDED USE

Lapro-Clip™ absorbable ligating clip cartridges are intended for use as absorbable ligatures. Lapro-Clip™ absorbable ligating clip cartridges are radiotransparent and will not interfere with interpretations of post-operative X-ray, CT, or MRI scans. The Lapro-Clip™ absorbable ligating clip cartridge may be used for ligation of the cystic artery and cystic duct and other general ligation.

SUMMARY COMPARING THE TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICES:

The proposed Lapro-Clip™ Auto Suture™ Reusable Long Clip Applier manufactured with a longer shaft length and tested to update sterilization, cleaning and lifecycle testing to current FDA Draft Guidance for "Processing/Reprocessing Medical Devices in Health Care Settings" is equivalent to Lapro-Clip™ Auto Suture™ Reusable Standard and Short Clip Applier (K925602) in terms of the following technological characteristics:

- Indication
- Raw materials
- Performance characteristics
- Biocompatibility
- Stability
- Life Cycle Reliability

Biocompatibility studies were conducted on existing Lapro-Clip™ Auto Suture™ Reusable Standard and Short Clip Applier (K925602). The proposed device contains same materials as predicate.

Sterilization and cleaning studies for the proposed Lapro-Clip™ Auto Suture™ Reusable Long Clip Applier and predicate device Lapro-Clip™ Auto Suture™ Reusable Standard and Short Clip Applier (K925602) have been performed.

Performance studies were conducted to demonstrate that the proposed device, the Lapro-Clip™ Auto Suture™ Reusable Long Clip Applier is substantially equivalent to the predicate device. In-vitro testing that supports the intended use of this device includes:

<u>In-vitro Testing:</u>

- Visual Examination
- Firing Force
- Cartridge Latch Depression
- Trigger Return Force
- General Safety and Efficacy

	▪ Leak Resistance ▪ Barrel Rotation Torque ▪ Clip Formation/Deployment ▪ Lifecycle reliability test In-vivo testing was not performed for this change. The clip cartridge with clips is sold separately and was previously tested in original 510(k) for clip applier and clip cartridge (K925602). This modification had no impact to clip cartridge or clips.
CONCLUSION:	The results of testing demonstrate that the modified the Lapro-Clip™ Auto Suture™ Reusable Long Clip Applier is substantially equivalent to the legally marketed Lapro-Clip™ Auto Suture™ Reusable Clip Applier (K925602).